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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,572	05/25/2006	Marie-Ange Juliette Etienne Badet-Denisot	0508-1155	1034
<div>466 7590 02/19/2009</div> <div>YOUNG & THOMPSON 209 Madison Street Suite 500 ALEXANDRIA, VA 22314</div>				
EXAMINER				
FRONDA, CHRISTIAN L				
ART UNIT		PAPER NUMBER		
1652				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/563,572

Applicant(s)

BADET-DENISOT ET AL.

Examiner

CHRISTIAN L. FRONDA

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20, 26-29 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 26-29 and 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 20, 26-29, 31-36 as listed in the claim set filed 11/18/2008 are pending and under consideration in this Office Action. New additional grounds of rejection are presented in the instant Office Action.
2. The rejection of claims 20, 26-29, 32, and 36 under 35 USC 101 has been obviated by the claim amendment and arguments filed 11/18/2008.
3. The rejection of claims 20, 27-29, and 32-36 under 35 U.S.C. 112, second paragraph, has been obviated by the claim amendment and arguments filed 11/18/2008.
4. The rejection of claims 20, 27-29, and 31-36 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been obviated by the claim amendment and arguments filed 11/18/2008.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the phrase "An isolated acid" which renders the claim vague and indefinite since the meaning of the phrase is not known and not defined by the specification. Appropriate correction is requested.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 20, 26-29, 33-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated protein of consisting SEQ ID NO: 8 encoded by the nucleic acid of SEQ ID NO: 7, an isolated protein of consisting SEQ ID NO: 10 encoded by the nucleic acid of SEQ ID NO: 9, and an isolated protein of consisting SEQ ID NO: 12 encoded by the nucleic acid of SEQ ID NO: 11, a eukaryotic or prokaryotic vector comprising said nucleic acid of SEQ ID NO: 7, SEQ ID NO: 9, or SEQ ID NO: 11; **does not** reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The arguments filed 11/18/2008 have been fully considered but are not persuasive.

According to MPEP 2164.01(a), factors considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

MPEP § 2164.04 states that while the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the

scope of protection sought by the claims. Accordingly, the factors most relevant to the instant rejection are addressed in detail below.

The nature and breadth of the claims encompass any enzymatically active protein having GFAT activity for which no specific full-length sequence and structure is apparent for the encompassed bacterial, eukaryotic or human GFAT sequence having the recited partial sequences of SEQ ID NOs: 2, 4, 6, or 14, having a purification tag inserted between two consecutive amino acids.

The reference of Chica et al. (Curr Opin Biotechnol. 2005 Aug;16(4):378-84; PTO 892) teaches that the complexity of the structure/function relationship in enzymes has proven to be the factor limiting the general application of rational enzyme modification and design, where rational enzyme modification and design requires in-depth understanding of structure/function relationships. The reference of Sen et al. (Appl Biochem Biotechnol. 2007 Dec;143(3):212-23; PTO 892) teaches *in vitro* recombination techniques such as DNA shuffling, staggered extension process (StEP), random chimeraesis on transient templates (RACHITT), iterative truncation for the creation of hybrid enzymes (ITCHY), recombined extension on truncated templates (RETT), and so on have been developed to mimic and accelerate nature's recombination strategy. However, such directed evolution techniques only enable methods for searching and screening for the claimed proteins having GFAT activity.

The specification provides guidance, prediction, and working examples for an isolated protein of consisting SEQ ID NO: 8 encoded by the nucleic acid of SEQ ID NO: 7, an isolated protein of consisting SEQ ID NO: 10 encoded by the nucleic acid of SEQ ID NO: 9, and isolated protein of consisting SEQ ID NO: 12 encoded by the nucleic acid of SEQ ID NO: 11. However, the specification does not provide guidance, prediction, and working examples for making and/or using the invention as claimed.

There is no teaching in the specification regarding the specific full-length sequence and structure of the claimed proteins and which amino acid residues can be altered as claimed while retaining GFAT activity. There is no teaching in the specification regarding which amino acid residues in the amino acid sequence of the protein where suppression, insertion or mutation of any amino acid can be made while retaining GFAT activity. Thus, one of ordinary skill in the art would not be able to identify the specific amino acid residues in the protein that can be altered as

claimed without further testing and/or testing all the possibilities, where the protein still retains GFAT activity.

The specification does not provide a correlation between any structure and GFAT activity, other than SEQ ID NOs; 8, 10, and 12, based on which those of ordinary skill in the art could predict which amino acids can have an insertion of any purification tag without losing catalytic activity. Further, there is no art-recognized correlation between any structure and GFAT activity, other than SEQ ID NOs; 8, 10, and 12, based on which those of ordinary skill in the art could predict which amino acids can have an insertion of any purification tag without losing catalytic activity.

Thus, one must perform an enormous amount of trial and error experimentation to search and screen for the claimed proteins from any biological source or synthesize the proteins and determine if the proteins still retain GFAT activity upon insertion of any purification tag sequence. General teaching regarding screening and searching for the claimed invention using activity assays stated in the specification is not guidance for making the claimed invention.

Therefore, in view of the overly broad scope of the claims, the specification's lack of specific guidance and prediction, the specification's lack of additional working examples, and the amount of experimentation required; it would require undue experimentation for a skilled artisan to make and use the claimed invention commensurate in scope with these claims. Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)).

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 6:30PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/
Primary Examiner
Art Unit 1652